



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Minneapolis District Office
Central Region
212 Third Avenue South
Minneapolis, MN 55401
Telephone: (612) 758-7114
FAX: (612) 334-4134

April 13, 2005

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 05 - 12

Lynn R. Gordon
President
French Meadow Bakery, Inc.
2610 Lyndale Avenue South
Minneapolis, Minnesota 55408

Dear Ms. Gordon:

On December 20 and 22, 2004, an investigator from the Food and Drug Administration, conducted an inspection of your facility at 2610 Lyndale Avenue South, Minneapolis, Minnesota. During this inspection, the investigator collected label samples from several of your firm's products. After reviewing the labeling for your products Healthy Hemp Sprouted Bread, Health Seed Spelt Wheat-Free Yeast-Free Bread, and Cinnamon Raisin Spelt Yeast Free-Organic Bread (each in 24 ounce packages) FDA concludes that these products violate provisions of the Federal Food, Drug, and Cosmetic Act (the Act). Regulations implementing requirements of the Act are found in Title 21, Code of Federal Regulations (21 CFR). Links to the Act and its regulations may be found at our web site, www.fda.gov.

Healthy Hemp Sprouted Bread

The product labeling includes the statement, "hempseed is one of the most nutritious plant foods available with ... a near-perfect composition of the essential fatty acids, Omega 3 & 6. These 'good fats' are necessary for optimum health by lowering cholesterol...." This claim indicates that the product is intended for use in treatment, prevention, or mitigation of hypercholesteremia and other cardiovascular diseases. Such claims are evidence that the product is intended for use as a drug within the meaning of section 201(g)(1)(B) of the Act [21 U.S.C. 321(g)(1)(B)].

Furthermore, your product is not generally recognized as safe and effective for the above referenced conditions and therefore, the product is also a "new drug" under section 201(p) of the Act [21 U.S.C. 321(p)]. New drugs may not be legally marketed in the United States without prior approval from FDA as described in

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section 505(a) of the Act [21 U.S.C. 355(a)]. FDA approves a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate that the drug is safe and effective.

Your product is also misbranded under section 502(f)(1) of the Act [21 U.S.C. 352(f)(1)] because the labeling for this drug fails to bear adequate directions for use.

Even if your product did not include claims that caused it to be a drug, it is a misbranded food. Your product is misbranded under section 403(r)(1)(A) of the Act [21 U.S.C. 343(r)(1)(A)] because the product label bears nutrient content claims but the product does not comply with the regulation that would allow it to bear such claims. When used to describe the level of a nutrient, the terms "rich in" and "high" are defined by regulation to mean that the product contains 20% or more of the Daily Reference Value (DRV) or Recommended Daily Intake (RDI) of that nutrient per reference amount customarily consumed [21 CFR 101.54(b)(1)]. The label of your product bears the claims, "rich source of minerals" and "High in ... Minerals;" however, the product is labeled to contain less than 20% of the RDI for all the minerals declared in the Nutrition Facts panel (iron, zinc, magnesium, selenium, phosphorus, and calcium).

In addition, the product is misbranded under section 403(q) of the Act [21 U.S.C. 343(q)] because the product label bears the claim "rich sources of ... vitamin E," but fails to include the amount per serving of vitamin E as a percent of the RDI, as required by regulation [21 CFR 101.9(c)(8)(ii)]. If this product does not contain at least 20% of the RDI of vitamin E per reference amount customarily consumed, it cannot bear a "rich source" claim for vitamin E.

Health Seed Spelt Wheat-Free Yeast-Free Bread

Your product is misbranded under section 403(r)(1)(A) of the Act [21 U.S.C. 343(r)(1)(A)] because the label bears a nutrient content claim but the product does not comply with the regulation which would allow it to bear such a claim. When used to describe the level of a nutrient, the term "high" is defined by regulation to mean that the product contains 20% or more of the RDI or DRV of the nutrient per reference amount customarily consumed [21 CFR 101.54(b)(1)]. The label of your product states, "High in Protein;" however, the product is labeled to contain approximately 14% of the DRV of protein, per reference amount.

Your product is further misbranded under section 403(a)(1) of the Act [21 U.S.C. 343(a)(1)] because the claim on the label that the product is "Wheat Free" is false and misleading. The product is labeled to contain spelt, a species of wheat.

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Cinnamon Raisin Spelt Yeast Free-Organic Bread

The product labeling includes the statement "Our yeast-free breads have been recommended for individuals with allergies, digestive problems, candida & diabetes." This claim indicates that the product is intended for use in treatment or mitigation of the named diseases. Such claims are evidence that the product is intended for use as a drug within the meaning of section 201(g)(1)(B) of the Act [21 U.S.C. 321(g)(1)(B)].

Furthermore, your product is not generally recognized as safe and effective for the above referenced conditions and therefore, the product is also a "new drug" under section 201(p) of the Act [21 U.S.C. 321(p)]. New drugs may not be legally marketed in the United States without prior approval from FDA as described in section 505(a) of the Act [21 U.S.C. 355(a)]. FDA approves a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate that the drug is safe and effective.

Your product is also misbranded under section 502(f)(1) of the Act [21 U.S.C. 352(f)(1)] because the labeling for this drug fails to bear adequate directions for use.

We request that you notify this office in writing within 15 working days of receipt of this letter stating the actions you will take to correct the violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Failure to make prompt corrections may result in further enforcement action being initiated by the Food and Drug Administration. This could include seizure of illegal products and injunction against the manufacturer of illegal products.

In addition to the violations described above, FDA has the following comments concerning your product labels:

- The ingredients lists for several of your products, such as Healthy Hemp Sprouted Bread, identify ingredients using terms other than their common or usual names. For example, an ingredient in the Healthy Hemp Sprouted Bread lists "Celtic Sea Salt®." As stated in 21 CFR 101.4, the ingredient statement must list ingredients by common or usual name. The names should not include trade names or other extraneous material.
- Several of your products, including your Healthy Hemp Sprouted Bread, Fat Flush Tortillas, and Cinnamon Raisin Spelt Bread, bear claims suggesting the absence of genetically modified organisms, such as "Non GMO" and

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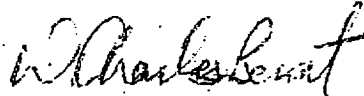
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"Contains NO GMO'S." As explained in the enclosed FDA Draft Guidance for Industry regarding "Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering," the claim "GMO free" is not technically accurate and may be misleading. We recommend that you use this guidance document to develop an accurate statement regarding your food and biotechnology.

This letter does not represent a comprehensive review of all of the products distributed by your firm; nor does it represent a complete review of all product labeling, which may include (among other materials) product brochures, product catalogs, newsletters and Internet web sites, as applicable. As owner, it is your responsibility to ensure that all products distributed by your firm are in compliance with the Act and its implementing regulations.

Your reply should be directed to Compliance Officer Tyra S. Wisecup at the address indicated in the letterhead. Ms. Wisecup may be reached at (612) 758-7114.

Sincerely,



W. Charles Becoat
Director
Minneapolis District

TCP
TSW/ccl

Enclosure (1)